K050568

JUN 1 - 2005

Orthelution Co.,Ltd. **ORLUS MINI SCREW**
#416-1, Room 207, Duchon B/D., Seongnae-dong, Gangdong-ku, Seoul, Korea
☎ +82 2 483-1212 Fax: +82 2 478-0735 **www.orthelution.com**

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: February 24, 2005

1. Company making the submission:

	Company
Name	Orthelution Co., Ltd.
Address	207 Dunchon B/D., #416-1 Seongnae-Dong, Gangdong-Gu, Seoul, Korea
Phone	+ 82 2-483-1212
Fax	+ 82 2-478-0735
Contact	J. M. Kim / president
Internet	Doldol22@netian.com

2. Device:
   Proprietary Name – ORLUS mini screw
   Common Name – Small bone screw
   Classification Name – Endosseous dental implant

3. Predicate Device:

   Osterned Orthodontic Screw System, OsteoMed L.P., K031936
   Dual Top Anchor System Screws, Jeil Medical Corporation, K033767

4. Classifications Names & Citations:

   21CFR 872.3640, DZE, Endosseous dental implant, Class2

5. Description:

   ORLUS mini screw is intended to provide a fixed anchorage for orthodontic movement of teeth. It is 1.6 and 1.8 mm in diameter and range from 5-14mm in total length and is made of Titanium 6Al-4V alloy. There are dual heads in the screw with which a wire can be hung to fix the maxilla and mandible. It is used temporarily and is removed after orthodontic treatment has been completed. It is supplied sterile and intended for single use only.

000007

K050568

6. Indication for use:

The ORLUS mini screw is intended for use as temporary anchor for orthodontic treatment.

7. Contra-indications:

1) Osteoporosis
2) Advanced diabetes
3) Metal allergies

8. Review:

ORLUS mini screw has the same device characteristics as the predicate device. Material, design and use concept is similar.

ORLUS mini screw has been subjected to extensive safety, performance, and product validations prior to release. Safety tests have been performed to ensure the devices comply to applicable industry and US regulations.

An extensive review of literature pertaining to the safety and biocompatibility of ORLUS mini screw has been conducted. Appropriate safeguards have been incorporated in the design of ORLUS mini screw.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Ortholution Co., Ltd. concludes that ORLUS mini screw is safe and effective and substantially equivalent to predicate devices as described herein.

10. Ortholution Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA.

END

000008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 - 2005

Ortholution Company Limited
C/O Ms. Cathryn N. Cambria
Consultant
Arkin Consulting Group, LLC
1733 Canton Lane
Marietta, Georgia 30062

Re: K050568
Trade/Device Name: Orlus Mini Screw
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: DZE
Product Code: II
Dated: May 9, 2005
Received: May 11, 2005

Dear Ms. Cambria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

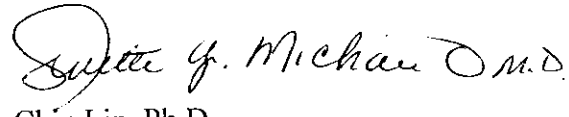
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050568

Device Name: Orlus Mini Screw

Indications for Use:
The Orlus Mini Screw is intended for use as a temporary anchor for orthodontic treatment.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K050568